

REMARKS

The Office Action dated December 13, 2005, has been fully considered. The present Amendment is intended to be a complete response thereto and to place the case in condition for allowance.

Claims 1-3 and 9-17 are pending. Claims 4-8 have been cancelled. Claim 1 has been amended. Support for the amendment is found, *inter alia*, in the specification on page 6, lines 5-10, and in claim 6 as originally filed.

THE CLAIMS ARE NOT ANTICIPATED OR OBVIOUS

Claims 1-17 stand rejected under 35 U.S.C. § 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over Perry (U.S. Patent No. 6,203,797). Applicant respectfully traverses the rejection.

To anticipate a claim, the reference must teach every element of the claim. *See* MPEP § 2131. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Perry fails to anticipate the present invention, because the reference fails to teach every element of the claimed invention. In particular, Perry fails to disclose the specific diseases

recited in claim 1, which include juvenile rheumatoid arthritis, multiple-sclerosis, autoimmune disease, Attention Deficit Disorder, Depression, bipolar disorder, Alzheimer's disease, Parkinson's Disease, Whipple's Disease, Tourette's Syndrome, Asperger's syndrome, Pervasive Development Disorder, early onset autism, regressive autism, Rhett's Syndrome, schizophrenia, obsessive-compulsive disorder, and chronic fatigue syndrome. These diseases are usually considered either autoimmune diseases or central nervous system (CNS) diseases.

Perry discloses a dietary supplement for alleviating symptoms of irritable bowel syndrome. The supplement contains freeze-dried aloe, fructo-oligosaccharides, and dahlia inulin juice mixture, and optionally friendly bacteria, such as *Lactobacillus bulgaricus*, *Lactobacillus acidophilus*, *Lactobacillus plantarum*, and *Bifidobacterium bifidum*, among other components, such as vitamin B6 (pyridoxine HCl), manganese and L-glutamine. Perry fails to disclose any of the diseases recited in claim 1.

In the Office Action, the Examiner alleges that “[t]he diseases treated which are not specifically mentioned in the reference are inherent to the cited disclosure because by administering the same composition the same effect is obtained.” See Office Action, page 3, lines 17-19. Applicant respectfully asserts that the present invention does not achieve the same effect as that disclosed by Perry. Perry alleviates symptoms of irritable bowel syndrome, while the present invention treats autoimmune or CNS diseases. Perry does not disclose, suggest, or otherwise remotely hint at the use of his composition in treating any of the diseases recited in the present claims.

Further, to rely on inherency, “the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied art.” *Ex parte Levy*, 17 USPQ2d 1461 (Bd.

Pat. App. & Inter. 1990) (emphasis in original). Moreover, “extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 49 USPQ2d 1949, 1950-1951 (Fed. Cir. 1999) (citations omitted). In the present case, the Examiner fails to show that the present invention “necessarily flows from the teachings” of Perry. As a matter of fact, this is not possible, because Perry only mentions treatment of irritable bowel syndrome. There is no showing, in the reference or in the art in general, that irritable bowel syndrome is connected or associated with any of the diseases recited in claim 1. The treatment of irritable bowel syndrome does not necessarily result in treatment of any of the diseases of claim 1, because a patient inflicted with irritable bowel syndrome may not have any of those diseases.

Moreover, Applicant respectfully refers the Examiner to *In re Marshall*, 198 USPQ 344 (CCPA 1978), which directs a result contrary to the Examiner’s position. In *In re Marshall*, the applicant claimed a weight control process involving anesthetizing nerve endings with an orally administered anesthetic of oxethazaine. The examiner rejected the claims as being inherently anticipated by the Physician’s Desk Reference (PDR) which disclosed oxethazaine for the treatment of esophagitis, gastritis, peptic ulcer and irritable colon syndrome. The court of appeals reversed the examiner’s and the Patent and Trademark Office Board of Appeals because “nothing in the PDR remotely suggests taking oxethazaine to lose weight.” *See Id.* at 347. Likewise, nothing in Perry suggests treatment of any of the diseases recited by the present invention. Therefore, the present invention is not anticipated by Perry. Accordingly, Applicant respectfully requests withdrawal of the rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *See* MPEP 2143.

Although the Examiner alleges, in the alternative, that the present invention is obvious over Perry, she fails to establish a *prima facie* case of obviousness, because she fails to provide any motivation to modify the teaching of Perry to arrive at the present invention. Nevertheless, Applicant respectfully asserts that the present invention is not obvious over Perry, because the reference fails to teach or suggest all the claim limitations. In particular, as discussed in detail above, Perry fails to teach or suggest the diseases recited in claim 1. Therefore, because Perry does not render the claimed invention obvious within the meaning of 35 U.S.C. § 103, Applicant respectfully requests withdrawal of the rejection.

DOUBLE PATENTING

Claims 1-17 stand provisionally rejected under nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application Serial No. 10/297,131. Applicant acknowledges the provisional rejection; however, because the claims of neither applications have been patented, a terminal disclaimer would be premature at this time. Therefore, Applicant respectfully requests the Examiner holding the rejection in abeyance until the claims of one the applications are patented.

CONCLUSION

Applicant has responded to the Office Action mailed September 13, 2005. All pending claims are now believed to be allowable and favorable action is respectfully requested.

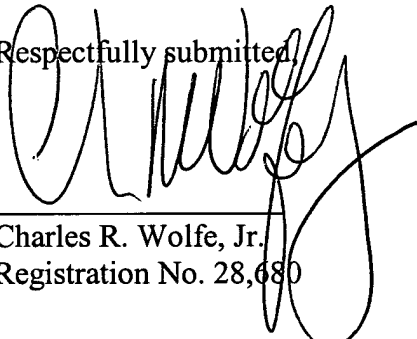
In the event that there are any questions relating to this Amendment or to the application in general, it would be appreciated if the examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (111828-00113). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, applicant hereby petitions under 37 C.F.R. 1.136(a) for an extension of time.

Any fees due are authorized above.

Date: 3/10/06

BLANK ROME LLP
Watergate
600 New Hampshire Avenue NW
Washington, DC 20037
Telephone: (202) 772-5800
Facsimile: (202) 772-5858

Respectfully submitted,

Charles R. Wolfe, Jr.
Registration No. 28,680